UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, ex. rel. CAMPIE *et al.*,

Plaintiffs,

v.

GILEAD SCIENCES, INC., *et al.*,

Defendants.
_____/

No. C-11-0941 EMC

ORDER DENYING DEFENDANTS' MOTION FOR PROTECTIVE ORDER OR, IN THE ALTERNATIVE, TO MAINTAIN INFORMATION UNDER SEAL

(Docket No. 46)

I. INTRODUCTION

This is a *qui tam* action by plaintiffs-relators Jeffrey Campie and Sherilyn Campie (collectively, "Relators") on behalf of Jeffrey Campie and the United States, twenty-two states, and the cities of New York and Chicago, against defendants Gilead Sciences, Inc. ("Gilead"), headquartered in Foster City, California and Gilead Sciences, ULC (collectively, "Defendants"). Gilead develops, manufactures, and sells drugs used to treat diseases like HIV/AIDS, hepatitis, and cystic fibrosis. Jeffrey Campie was formerly Gilead's Senior Director of Commercial Quality Assurance and Sherilyn Campie was an Associate Manager of Quality Control for Gilead.

Relators allege violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et. seq.*, and analogous state statutes and city ordinances, claiming that Gilead defrauded the federal, state, and local governments by selling billions of dollars' worth of nonconforming drugs, which were paid for through programs like Medicare, Medicade, and the President's Emergency Plan for AIDS Relief.

The case is currently entirely under seal. Even the existence of the suit is undisclosed and the case is titled "*Underseal v. Underseal*" on the Court's public notices. Pending before the Court is Defendants' motion to maintain the case under seal (the "Motion"), until the disposition of Gilead's motion to dismiss the First Amended Complaint (the "FAC"), which is set for hearing on September 11, 2014. This Motion is fashioned as a Motion for a Protective Order, or alternatively, as an Administrative Motion to File Under Seal pursuant to Civil Local Rule 79-5.

The Court **DENIES** the Motion for the reasons set forth below. The parties shall meet and confer and submit within 14 days of this order a redacted version of the FAC.

II. FACTUAL AND PROCEDURAL BACKGROUND

Relators provide a summary of key allegations in the FAC:

> Gilead manufactured and distributed drug products that failed to meet applicable specifications because they (1) were contaminated with a host of adulterants, including, but not limited to, arsenic, cadmium, mercury, lead, nickel, steel, titanium, chromium, iron, cobalt, aluminum, metal shards, glass, rubber, polyethylene (plastic), stones or pebbles, cement, paint, wood fibers and fibrous building materials, organic material, microbes (including bacillus cereus), paper, Teflon, acetaminophen, other degradants, and blood; (2) were improperly manufactured using active pharmaceutical ingredients ("API") sourced on the cheap from unregistered facilities in China and otherwise in violation of federal law and Good Manufacturing Practices; (3) were subjected to extreme storage and shipping conditions; and (4) lacked proper testing and analysis. FAC ¶¶ 3, 51-52, 57, 68, 70, 138, 160, 185, 192, 202-213, 220-224, 234-243, 680, 682. These nonconforming drugs were paid for by the government through programs like Medicare, Medicaid and the President's Emergency Plan for AIDS Relief. FAC ¶¶ 1, 15-18, 43-44, 470, 476, 482.

Relators' Response to Defendants' Motion ("Opp.") (Docket No. 63) at 2.

When Jeffrey Campie raised concerns about Gilead's false payment claims for the non-conforming drugs, he was retaliated against and ultimately terminated. Campie Decl. ¶ 19 (Docket No. 65). Among the alleged violations of the False Claim Act are "knowingly present[ing] . . . a false or fraudulent claim for payment or approval" and retaliatory termination. FAC ¶¶ 470, 684 (citing 31 U.S.C. §§ 3729(a)(1)(A), 3730(h)).

The original complaint was filed under seal, as required for civil actions alleging violations of the False Claim Act that are brought on behalf of the United States Government (the "Government"). *See* 31 U.S.C. § 3730 (b)(2). The False Claims Act requires the complaint to

remain under seal for at least 60 days to provide the Government time to decide whether to intervene. The Government received extensions of time, and on February 19, 2013, it notified the Court that it declined to intervene, but that it would continue to allow the action to be brought on its behalf. *See* Docket No. 16 (citing 31 U.S.C. § 3730(b)(1)).

The seal remained in place, however, and Gilead became aware of this action on April 10, 2014, shortly before it was served with the FAC. Mot. at 4; Docket Nos. 26, 27. The parties stipulated to maintaining the original complaint and exhibits under seal, without prejudice to unsealing the FAC, since the original complaint and exhibits were no longer operative and would have no bearing on the resolution of the action. Docket No. 54.

In the Motion, Gilead moves to maintain the action under seal until the disposition of its motion to dismiss, scheduled for hearing on September 11, 2014. This appears to be based on its belief that it will prevail on its motion to dismiss, and unless Relators have stated a claim, that it would be harmful to publicly disclose the allegations in the FAC. *See* Reply ISO Defendants' Motion for Protective Order (Docket No. 68) at 13. Relators object to keeping the entire case under seal, but are willing to redact specific allegations that Gilead identifies as containing "genuine trade secrets." Opp. at 1. The United States, as a real party in interest (*see U.S. ex rel. Killingsworth v. Northrop Corp*., 25 F.3d 715, 720 (9th Cir. 1994)), also requests the Court to unseal the case and only maintain under seal portions that "warrant protection under Civil L.R. 79-5 or other such authority." United States Position on Defendants' Motion for Protective Order (Docket No. 73) at 3.

III. DISCUSSION

Gilead asserts that the FAC should remain under seal because: (1) the FAC contains confidential and trade secret-related information, and line-by-line redaction would not only be burdensome for the Court and the parties, "the degree of redaction required would make the remaining pieces of unredacted text effectively meaningless" (Mot. at 4, 10); (2) disclosure of the information in the FAC could potentially harm patients who use Gilead drugs because it "could induce some patients to stop using Gilead's drugs" when "careful adherence to a strict medication regiment is critical to their health" (Mot. at 9-10); and (3) it would be "inequitable" to allow

Relators to publicly disclose confidential information in the FAC, when Relators signed confidentiality agreements with Gilead "not to disclose company information" (Mot. at 5).

Relators respond that Gilead's confidentiality and trade secret contentions are "sweeping conclusory statements" lacking the requisite specificity (Opp. at 7); that "the vast majority" of the information in the FAC is publicly available, in some cases disclosed by Gilead itself in press releases and public filings (Opp. at 1, 8); and that retaining copies of incriminating documents is "a protected practice under the False Claims Act, which cannot be circumvented by corporate confidentiality agreements" (Opp. at 2).

A. Legal Standard

"Two standards generally govern motions to seal documents . . . . First, a 'compelling reasons' standard applies to most judicial records. This standard derives from the common law right 'to inspect and copy public records and documents, including judicial records and documents.'" *Pintos v. Pac. Creditors Ass'n*, 605 F.3d 665, 678 (9th Cir. 2010) (quoting *Nixon v. Warner Commc'ns, Inc*., 435 U.S. 589, 597 & n.7). "[A] 'strong presumption in favor of access' is the starting point." *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. 2006) (quoting *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003)). To overcome this strong presumption, the party seeking to seal a judicial record must "articulate compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process" and "significant public events." *Id.* at 1178-79 (internal citations, quotation marks, and alterations omitted). "In general, 'compelling reasons' sufficient to outweigh the public's interest in disclosure and justify sealing court records exist when such 'court files might have become a vehicle for improper purposes,' such as the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." *Id*. at 1179 (citing *Nixon*, 435 U.S. at 598). *See also, Nixon*, 435 U.S. at 598 (noting that some courts have sealed "business information that might harm a litigant's competitive standing"). The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records." *Id.*

The court must "balance the competing interests of the public and the party who seeks to keep certain judicial records secret. After considering these interests, if the court decides to seal certain judicial records, it must base it decision on a compelling reason and articulate the factual basis for its ruling, without relying on hypothesis or conjecture." *Id.* at 1179.

Civil Local Rule 79-5 supplements the compelling reasons standard set forth in *Kamakana*: the party seeking to file in the Court a document or portions of it under seal must "establish[] that the document, or portions thereof, are privileged, protectable as a trade secret or otherwise entitled to protection under the law. . . . The request must be narrowly tailored to seek sealing only of sealable material." Civil L.R. 79-5(b).

The second standard is a "good cause" standard. It applies to "private materials unearthed during discovery, as such documents are not part of the judicial record. Rule 26(c) of the Federal Rules of Civil Procedure governs here, providing that a trial court may grant a protective order 'to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.'" *Pintos*, 605 F.3d at 678 (internal citation omitted). "This 'good cause' standard presents a lower burden for the party wishing to seal documents than the 'compelling reasons' standard. The cognizable public interest in judicial records that underlies the 'compelling reasons' standard does not exist for documents produced between private litigants," *id.*; "much of the information that surfaces during pretrial discovery may be unrelated, or only tangentially related, to the underlying cause of action. Therefore, restraints placed on discovered, but not yet admitted, information are not a restriction on a traditionally public source of information." *Foltz*, 331 F.3d at 1134 (citation and quotation marks omitted). The "good cause" standard also applies to "previously sealed discovery attached to a nondispositive motion" for similar reasons: "Nondispositive motions are often unrelated, or only tangentially related, to the underlying cause of action, and, as a result, the public's interest in accessing dispositive materials does not apply with equal force to non-dispositive materials." *Pintos*, 605 F.3d at 678 (internal citations and quotation marks omitted).

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B. Application

1. The "Compelling Reasons" Standard Applies

While the Ninth Circuit has not specifically addressed which of the two standards applies to a complaint, considering the rationale that underlies each, the Court has little doubt that the "compelling reasons" standard applies. As a preliminary matter, the seal provision of the False Claims Act, 31 U.S.C. § 3730(b)(2), provides no basis for maintaining the FAC under seal, since the purpose of the seal provision is to allow "the government the opportunity to study and evaluate the relator's information for possible intervention in the *qui tam* action or in relation to an overlapping criminal investigation," and the Government has already decided not to intervene. *United States ex. rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 245 (9th Cir. 1995); Docket No. 16.

The "compelling reasons" standard should apply to the FAC because a complaint is undoubtedly part of the "judicial record." It must be filed with the court. Here, moreover, the public interest in disclosure of the FAC is heightened due to the allegations that implicate the health of those who use Gilead's drugs. Further, the rationale for applying the "good cause" standard does not apply. As Judge Armstrong held:

> Under the Ninth Circuit's jurisprudence in *Kamakana*, a request to seal all or part of a complaint must clearly meet the "compelling reasons" standard and not the "good cause" standard. . . . [The complaint] is the root, the foundation, the basis by which a suit arises and must be disposed of. . . . [I]t is the means by which a plaintiff invokes the authority of the court, a public body, to dispose of his or her dispute with a defendant. Thus, this Court cannot conclude a complaint is "unrelated, or only tangentially related, to the underlying cause of action." It *provides* the causes of action. Likewise, this Court cannot conclude sealing parts of a complaint is analogous to sealing records "not directly relevant to the merits of the case." It *establishes* the merits of a case, or the lack thereof.

In re NVIDIA Corp. Derivative Litig., C 06-6110 SBA, 2008 WL 1859067 (N.D. Cal. Apr. 23, 2008) (emphasis in original) (quoting *Kamakana*, 447 F.3d at 1179).

Thus, to seal the FAC or portions thereof, Gilead must "articulate compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure." *Kamakana*, 447 F.3d at 1178-79.

2. Gilead's Claims of Trade Secrets and Confidential Business Information

Gilead repeatedly asserts that its trade secrets and confidential pharmaceutical information are protected by law and cites numerous authorities in support. However, this is undisputed. At issue is what information in the FAC constitutes trade secrets or confidential business information.

a. Gilead Fails to Meet the Narrow Tailoring Requirement of Civil L.R. 79-5

Gilead names four categories of "confidential and trade-secret related information": (1) "supply chain, manufacturing processes, and underlying business relationships"; (2) "quality system and product specifications"; (3) "clinical trials and drug development"; and (4) "business strategies and plans." Docket No. 47 ("Colomb Decl."). It claims that public disclosure of such information "poses a high risk of competitive harm." Mot. at 8.

The breadth of information that arguably fits under these categories is vast. For example, "quality system" in (2) is defined to be "formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement." Colomb. Decl. ¶ 13 (quoting FDA, *Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations* (Sep. 2006)). Given such broad descriptions, it is no surprise that Gilead can fit all paragraphs ¶¶ 51-465 in the FAC into one of these categories. *See* Colomb Decl.

However, even a cursory look at the FAC reveals that not all of this information could constitute confidential information. For example, Gilead asserts that ¶¶ 103-127 "discuss technical regulatory issues related to Gilead commercial product, particularly drug product that has FTC as a component API." *Id.* ¶ 25. Gilead asserts that this information "reveals core aspects of Gilead's dealing with suppliers and customers" and "core details regarding Gilead's quality systems and processes," which is "Gilead's proprietary information and potentially sensitive information from [sic] third parties." *Id.* But take for example FAC ¶ 103, which arguably contains information about Gilead's "quality systems" (rather than dealings with suppliers/customers):

> As reflected herein, the defendants had ongoing problems with contaminants in their API and final drug products. Gilead knows about these problems and has documented them extensively, yet takes active steps to: (I) conceal the issues from the government; and (ii)

> avoid destroying contaminated batches or recalling drugs that have already been sold commercially.

FAC ¶ 103. This does not constitute protectable information.

Of course, Gilead may want to keep such allegations from public disclosure, but "the mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records." *Kamakana*, 447 F.3d at 1179. Gilead must narrowly tailor its request to seal information that genuinely constitutes trade secrets or confidential information in accordance with Civil L.R. 79-5.

b. Gilead May Not Seal Information That Is Publicly Available

Some allegations in the FAC appear on their face to constitute confidential business information or trade secrets. However, Relators assert that much of this information has been publicly disclosed. "Information that is public knowledge or that is generally known in an industry cannot be a trade secret," *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984), nor can Gilead claim that disclosure of such information in the FAC would cause it competitive harm. Put differently, Gilead's claims to protection for trade secrets and confidential business information are not supported by "specific factual findings" as required under *Kamakana*.

For example, Gilead's Vice-President of Chemical Manufacturing, Matthew Colomb, states in his declaration that "the identities of the specific CMOs [contract manufacturing organizations] all constitute highly confidential commercial information," explaining, "[a] competitor could approach a CMO it knows is working with Gilead with slightly more attractive commercial terms and capture that CMO's manufacturing capacity, thereby depriving Gilead of its investment in developing that CMO and its future supply of drugs from the CMO." Colomb Decl. ¶ 11. But Jeffrey Campie, in his declaration, provides website addresses where the identities of the key CMOs in the FAC and the API [active pharmaceutical ingredients] they manufacture for Gilead are disclosed. For example, one website purportedly discloses that Synthetics China manufactures for Gilead emtricitabine, which is listed as an API on the drug labels of Gilead's drugs Truvada, Emtriva, Emtriva Oral Solution, Atripla, and Complera. Campie Decl. at 15, 18 of 26. In its Reply, Gilead appears to

retreat from Colomb's statement above, instead pointing to more detailed allegations in the FAC about Gilead's use of CMOs.

As another example, Colomb declares that the FAC divulges information about clinical trials for Gilead's drug Hepsera, including "clinical study results" which "could be misappropriated by competitors." Colomb Decl. ¶ 36. Yet Campie provides website addresses where information about the Hepsera clinical trial is purportedly disclosed, including "the study design, drugs/APIs involved, study outcomes," etc. Campie Decl. at 24 of 26.

Similar examples abound. Under *Kamakana*, Gilead may not seal information that is publicly available claiming that it is confidential and trade-secret related. *Kamakana*, 447 F.3d at 1178-79.

c. Line-by-Line Redaction Is Warranted

Gilead asserts that line-by-line redaction is impracticable and burdensome for the Court and the parties, and that "the redaction required would make the remaining pieces of remaining text effectively meaningless." Mot. 10. The Court is not persuaded. As discussed above, Gilead's claims to protection are overbroad and there is no compelling reason to seal the entire FAC. The parties shall meet and confer to determine which portions are sealable in accordance with the above.

3. Gilead's Argument That Disclosure Would Harm Patients Lacks Merit

Gilead argues that public disclosure of the FAC "could pose serious harm to patients who rely on Gilead's life-saving medicines, by suggesting that patients should interrupt their treatment regimens out of concern for the safety of those medicines." Reply at 2. It analogizes to public notifications of recalls where, "[t]he Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential." 21 C.F.R. § 7.50.

Gilead's reliance on the FDA's regulation is misplaced. Under section 7.50, a decision to delay public notification is made after the FDA determines that public notification would cause unnecessary anxiety in patients. Here, of course, no such determination has been made. Further, while the FDA might delay a public notification, a recalling firm must "promptly notify each of its

affected direct accounts of the recall" and, among other things, explain "the reason for the recall and the hazard involved." 21 C.F.R. § 7.49. Therefore, section 7.50 may be understood not as an attempt to prevent disclosure of the recall, but to make it more likely patients receive information of the recall through their physicians. Here, Gilead is not attempting to make the information in the FAC available through other channels. Nor do allegations in a complaint necessarily carry as much weight as a recall notification by the FDA. If anything, disclosure of the FAC may serve the purpose of section 7.50 by leading patients to consult with their physicians about Gilead's drugs they are taking.

Thus, the risk of harm to patients stemming from disclosure of the FAC does not constitute a compelling reason to seal the FAC.

4. Confidentiality Agreements Signed by Relators Do Not Justify Sealing

Gilead asserts that "it would be inequitable to allow Relators to bootstrap confidential information that Relators previously pledged to protect into a public filing." Mot. at 6. Each Relator signed an Employee Confidential Information and Inventions Agreement ("Confidentiality Agreement") agreeing not to disclose "Confidential Information," defined as "any non-public information of Gilead in any form that relates to Gilead's actual or anticipated business, research or development, technical data, trade secrets or know-how." Docket No. 69 Exhs. A, B. Relators do not contest that they may be in breach of the Confidentiality Agreements, but assert that for reasons of public policy "corporate confidentiality agreements are not enforceable to preclude a relator from preserving and using contemporaneously obtained copies of documents relating to his or her FCA claim." Opp. at 13.

Precluding Relators from disclosing "Confidential Information" in the FAC on the basis of the Confidentiality Agreements "would frustrate Congress's purpose in enacting the False Claims Act – namely, the public policy in favor of providing incentives for whistleblowers to come forward, file FCA suits, and aid the government in its investigation efforts." *Siebert v. Gene Sec. Network, Inc*, No. 11-CV-01987-JST, 2013 WL 5645309 (N.D. Cal. Oct. 16, 2013) (holding that a confidentiality agreement "not to retain or disclose the confidential documents that form the basis of this action is unenforceable as a matter of public policy"). *Cf. Brado v. Vocera Communications,*

Inc., 2014 WL 3752134 (N.D. Cal. July 30, 2014) (discussing public policy in favor of whistleblowers in conjunction with other factors to determine whether plaintiffs could use information covered by confidentiality agreements). Clearly, the FCA envisions information covered by such broad confidentiality clauses will be used in a *qui tam* action, as it "requires that a relator turn over all material evidence and information to the government when bringing a *qui tam* action." *U.S. ex rel. Ruhe v. Masimo Corp.*, 929 F. Supp. 2d 1033, 1039 (C.D. Cal. 2012) (citing 31 U.S.C. § 3730(b)(2)).

This is not to say that any Confidential Information may be publicly disclosed if for the purpose of this *qui tam* action. Relators are not arguing for disclosure beyond what is generally permitted and required under *Kamakana*. In this respect, Gilead's reliance on *U.S. ex rel. Westfall v. Axiom Worldwide, Inc.*, No. 8:06-cv-571-T-33TBM, 2008 WL 5341140 (M.D. Fl. Dec. 19, 2008) is misplaced. There, the court determined that the customer list and training manual that the relators sought to attach to their complaint genuinely constituted trade secrets and proprietary information. *Westfall*, 2008 WL 5341140 at *4. Moreover, the court found a seal was further warranted "to protect innocent third parties, as . . . the customer list contains very detailed contact information for physicians and other individuals who have not consented to disclosure of their personal information." *Id.* Here, in contrast, as discussed above, Gilead unjustifiably seeks to seal much more than trade secrets and proprietary information, and the privacy of innocent third parties is not at stake.

Thus, the Confidentiality Agreements do not provide grounds for sealing the FAC.

IV. CONCLUSION

For the reasons above, the Court **DENIES** Gilead's request to seal the entire FAC. The FAC may be redacted to the extent that it discloses trade secrets and genuine confidential business information. The parties shall meet and confer, stipulate to redactions, and file within 14 days of this order a redacted version of the FAC. Any redactions must be consistent with this order and comply with Civil L.R. 79-5.

In addition, the parties are **ORDERED TO SHOW CAUSE** within 14 days of this order why the Court should not lift the seal on this order, the papers already filed in conjunction with the

pending motion to dismiss, and all *future* filings in the Court subject only to sealing and redaction consistent with Local Rule 79-5. In responding, the parties shall stipulate to any proposed redactions to these filings. Other prior filings may remain under seal.

This order disposes of Docket No. 46.

IT IS SO ORDERED.

Dated: August 4, 2014

EDWARD M. CHEN
United States District Judge